

### **REMARKS**

This communication responds to the Final Office Action of March 31, 2009, in which Claims 1, 22, 23, 36, and 41-44 have been rejected under 35 U.S.C. § 102 and Claims 1, 22, and 23 have been rejected under 35 U.S.C. § 103. In view of the amendments and the following remarks, Applicants respectfully request reconsideration and allowance of the pending claims.

#### **Examiner Interview Summary**

Applicants' representative, Nathan Witzany, held an Examiner Interview with the Examiner on August 28, 2009. During the Interview, proposed amendments and the cited prior art were discussed. While no specific language was discussed with respect to the proposed amendments, Applicants believe the amendments herein are consistent with the substance of the discussions during the Interview.

#### **Claim Rejections Under 35 U.S.C. §102**

Claims 1, 22, 23, 36, and 41-44 were rejected under 35 U.S.C. § 102(b) as anticipated by McKinney (US 5,167,665). Applicants traverse the rejection for at least the following reasons.

Amended Claim 1 is directed to a fastener for stabilizing multiple bone fragments. The fastener comprises, in part, a "first portion having a cylindrical body including a longitudinal axis, the cylindrical body being curved along its longitudinal axis; and a . . . second portion having a cylindrical body including a longitudinal axis, the cylindrical body being curved along its longitudinal axis."

McKinney does not disclose, teach, nor suggest a first and second portion, each "having a cylindrical body including a longitudinal axis, the cylindrical body being curved along its longitudinal axis." Rather, McKinney discloses a rivet based on a conventional, commercially available blind rivet. Col. 3, ll. 29-30. The rivet 11 includes a body 19 and a mandrel 23. Col. 3, ll. 38-39. With regard to the body 19, McKinney discloses:

The rivet body 19 has a shank 25 and a head 33. The shank 25 is a cylindrical tube. The shank 25 has first and second ends 29, 31.

The head 33 is integral with the first end 29 of the shank 25. The head 33 extends transversely out from the shank . . . The body 19 has an interior passage (not shown) extending from the shank second end 31 to the head 33. The interior passage receives the mandrel 23. Col. 3, ll. 40-50.

With regard to the body 19, McKinney discloses:

The mandrel 23 is a shaft that extends through the body 19. One end of the mandrel has a bead 39 that is located adjacent to the shank second end 31. The bead 39 has a diameter that is larger than the inside diameter of the shank. The other end 41 of the mandrel 23 is free so as to be received by a rivet gun 47 (see FIG. 4). The body 19 is secured to the mandrel 23 so that sliding the body along the mandrel and rotating the body on the mandrel is difficult. Col. 3, ll. 57-65.

Figure 3 of McKinney illustrates the rivet body 19 and mandrel 23. As shown, the rivet body 19 and the mandrel 23 are linear and have substantially no curvature along a longitudinal axis.

During the Examiner Interview on August 28, 2009, the Examiner seemed to agree that McKinney does not explicitly disclose “having a cylindrical body including a longitudinal axis, the cylindrical body being curved along its longitudinal axis.”

Therefore, Claim 1 is patentable over McKinney. Claims 22 and 23 depend from Claim 1 and are patentable for the same reasons as Claim 1 and for the additional limitations recited therein.

Amended Claim 36 is directed to a method for operating a bone fastener used for stabilizing a plurality of bone fragments. The method comprises, in part, “wherein each of the first and second portions have a cylindrical body including a longitudinal axis, each cylindrical body being curved along its longitudinal axis.” Accordingly, for reasons similar to those provided above, Claim 36 is patentable over McKinney.

Additionally, amended Claim 36 comprises, in part, “displacing a distal end of a first portion of the bone fastener through at least one of the plurality of bone fragments; displacing a second portion of the bone fastener through and within the first portion such that an enlarged distal end of the second portion abuts the distal end of the first portion, so as to engage the first

and second portions of the fastener; and displacing the first and second engaged portions relative to one another to a locked position, wherein the bone fragments are secured by the locked in fastener between the enlarged distal end of the second portion and a proximal end of the first portion.”

McKinney does not disclose, teach, nor suggest a plurality of bone fragments “secured by the locked in fastener between the enlarged distal end of the second portion and a proximal end of the first portion.” Rather, McKinney discloses an object is aligned over bone so that the holes 59 in the object are aligned with holes 55 in the bone. Col. 4, ll. 28-29. A rivet 11 and the free end of the mandrel are inserted into the rivet gun 47, as shown in Figure 4. Col. 4, ll. 30-32. The rivet is inserted through one of the object’s holes 59 and one of the bone’s holes 55. Col. 4, ll. 35-36. Then, the rivet gun is actuated to set the rivet. Col. 4, ll. 39-40. When the rivet 11 is set, as shown in Figure 1, the object 13 is clamped to the cortex 53 of the bone 17 by the two heads 33, 49 of the rivet. Col. 4, ll. 57-59. Accordingly, McKinney merely discloses a method of attaching objects, such as plates, to bone. Col. 5, ll. 46-47.

In one embodiment, McKinney discloses:

[T]he bone 17 has a fracture 18 therethrough, which divides the bone into first and second segments 17A, 17B. The metal plate 14 extends across the fracture 18 and is attached to both the first and second segments 17A, 17B with the method of the present invention. The method uses the rivets 11 to attach the plate 14 to the bone. Col. 3, ll. 21-27.

McKinney does not, however, disclose a plurality of bone segments held by a single fastener, particularly wherein the plurality of bone fragments are “secured by the locked in fastener between the enlarged distal end of the second portion and a proximal end of the first portion.”

Therefore, Claim 36 is patentable over McKinney.

Amended Claim 41 is directed to a fastener for stabilizing multiple bone fragments. The fastener comprises, in part, a “first portion being a sleeve including a longitudinal axis, the sleeve being curved along its longitudinal axis; and a . . . second portion being a shaft including a

longitudinal axis, the shaft being curved along its longitudinal axis.” Accordingly, for reasons similar to those provided above, Claim 41 is patentable over McKinney.

Amended Claim 42 is directed to a method for operating a bone fastener used for stabilizing a plurality of bone fragments. The method comprises, in part, “displacing a distal end of a first portion of the bone fastener through at least one of the plurality of bone fragments; displacing a second portion of the bone fastener through and within the first portion such that an enlarged distal end of the second portion abuts the distal end of the first portion, so as to engage the first and second portions of the fastener; and displacing the first and second engaged portions relative to one another to a locked position, wherein the bone fragments are secured by the locked in fastener between the enlarged distal end of the second portion and a proximal end of the first portion.” Amended Claim 42 further comprises, in part, the “first portion comprises a sleeve including a longitudinal axis, the sleeve being curved along its longitudinal axis and wherein the second portion comprises a shaft including a longitudinal axis, the shaft being curved along its longitudinal axis.” Accordingly, for reasons similar to those provided above, Claim 42 is patentable over McKinney.

Amended Claim 43 is directed to a fastener for stabilizing multiple bone fragments. The fastener comprises, in part, a “first portion being a cylindrical rivet body including a longitudinal axis, the cylindrical rivet body being curved along its longitudinal axis; and a . . . second portion being an elongated mandrel including a longitudinal axis, the mandrel being curved along its longitudinal axis.” Accordingly, for reasons similar to those provided above, Claim 43 is patentable over McKinney.

Amended Claim 44 is directed to a method for operating a bone fastener used for stabilizing a plurality of bone fragments. The method comprises, in part, “displacing a distal end of a first portion of the bone fastener through at least one of the plurality of bone fragments; displacing a second portion of the bone fastener through and within the first portion such that an enlarged distal end of the second portion abuts the distal end of the first portion, so as to engage the first and second portions of the fastener; and displacing the first and second engaged portions relative to one another to a locked position, wherein the bone fragments are secured by the locked in fastener between the enlarged distal end of the second portion and a proximal end of

the first portion.” Amended Claim 42 further comprises, in part, the “first portion comprises a cylindrical rivet body including a longitudinal axis, the cylindrical rivet body being curved along its longitudinal axis and wherein the second portion comprises an elongated shaft including a longitudinal axis, the shaft being curved along its longitudinal axis.” Accordingly, for reasons similar to those provided above, Claim 44 is patentable over McKinney.

Reconsideration and allowance are respectfully requested.

### **Claim Rejections Under 35 U.S.C. §103**

Claims 1, 22, and 23 were rejected under 35 U.S.C. § 103(a) as unpatentable over Siekierski (US 6,470,709). Applicants traverse the rejection for at least the following reasons.

Amended Claim 1 comprises, in part, a “first portion having a cylindrical body including a longitudinal axis, the cylindrical body being curved along its longitudinal axis; and a . . . second portion having a cylindrical body including a longitudinal axis, the cylindrical body being curved along its longitudinal axis . . . wherein the curved cylindrical body of the second portion is slidably disposed within and extending substantially throughout the curved cylindrical body of the first portion.”

Siekierski does not teach nor suggest a fastener comprising, in part, a “wherein the curved cylindrical body of the second portion is slidably disposed within and extending substantially throughout the curved cylindrical body of the first portion.” Instead, Siekierski discloses a partial ring arrangement assembly 160 with an insertable and removable end piece 162. Col. 9, ll. 3-4. The end piece 162 includes a ball end piece 168 and a stem piece 170. Col. 9, ll. 13-15. Siekierski describes the stem piece 170 as follows:

A stem piece is made on a high modulus elasticity material, such as a Titanium or a spring steel (as shown with a negligible degree of bend-straight) such that when it is inserted into the end opening 172 so that it follows the central passage 174 of the partial ring piece 164 as [sic] it elastically deforms. FIG. 15 shows the end piece 162 inserted to the base of the ball 168. The elastic stem 170 has been bent by the curvature of the internal passage 174

to have a sideways high contact force at locations 180, 182, 184. Col. 9, ll. 19-28.

Accordingly, the stem piece 170 of Siekierski is substantially straight until inserted into the partial ring piece 164. Upon insertion, the elastic stem 170 is bent by the curvature of the internal passage 174 to create a binding/retaining force to hold the end piece and its ball 168 in position. Nowhere does Siekierski disclose, however, the elastic stem 170 extends substantially throughout the partial ring piece 164.

The Office notes the Federal Circuit has held:

[W]here the only difference between the prior art and the claims was a recitation of relative dimensions of the claimed device and a device having the claimed relative dimensions would not perform differently than the prior art device, the claimed device was not patentably distinct from the prior art device. Office Action, p. 5, citing *In Gardner v. TEC Systems, Inc.*, 725 F.2d 1338 (Fed. Cir. 1984).

It is asserted that Applicants' recitation of a "first portion having a cylindrical body including a longitudinal axis, the cylindrical body being curved along its longitudinal axis; and a . . . second portion having a cylindrical body including a longitudinal axis, the cylindrical body being curved along its longitudinal axis . . . wherein the curved cylindrical body of the second portion is slidingly disposed within and extending substantially throughout the curved cylindrical body of the first portion" is more than a simple recitation of relative dimension. The curved cylindrical body of the first portion and the curved cylindrical body of the second portion work together to allow the second portion to be disposed within and extend substantially throughout the first portion.

In contrast, as stated above, the stem piece 170 of Siekierski is substantially straight until inserted into the partial ring piece 164. Only upon insertion is the elastic stem 170 possibly bent by the curvature of the internal passage 174. The curvature of the internal passage 174 and the resistance caused by the straightness of the elastic stem 170 create a binding/retaining force to hold the end piece 162 and its ball 168 in position. Siekierski nowhere discloses how a straight stem would be configured to be slidingly disposed within and extend substantially throughout the partial ring piece and maintain the resistance caused by the straightness of the elastic stem 170 in

order to create the necessary binding/retaining force to hold the end piece 162 in position. Applicants respectfully assert that their claimed limitation has been improperly read into the disclosure of Siekierski using hindsight observations.

Accordingly, Claim 1 is patentable over Siekierski. Claims 22 and 23 depend from Claim 1 and are patentable for the same reasons as Claim 1 and for the additional limitations recited therein. For example, Claim 23 recites "wherein the distal end of the cylindrical body of the first portion is forced radially outwards from its longitudinal axis to abut an outer surface of another one of the multiple fragments in response to a tensile force applied to a proximal end of the second portion." Siekierski does not teach nor suggest a distal end of the partial ring piece is forced radially outwards from its longitudinal axis."

Reconsideration and allowance are respectfully requested.

### **Conclusion**

This response is being submitted on or before August 31, 2009, with a request for an extension of time to that date and the associated fee, making this a timely response. It is believed that no additional fees are due in connection with this filing. However, the Commissioner is authorized to charge any additional fees, including extension fees or other relief which may be required, or credit any overpayment and notify us of same, to Deposit Account No. 04-1420.

This application now stands in allowable form and reconsideration and allowance is respectfully requested.

Respectfully submitted,

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